UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,604	07/29/2003	Kei Roger Aoki	17328CON3	8682

7590 04/18/2006

Stephen Donovan
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,604	AOKI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,9,12,13 and 29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,9,12,13 and 29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on March 29, 2006 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1, 4, 5, 9, 12, 13 and 29-36 are pending.

Applicants' amendment filed March 29, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 12, 29, 31, 33 and 36 have been amended, and claim 28 has been cancelled. Therefore, claims 1, 4, 5, 9, 12, 13 and 29-36 are examined.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claim 28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 31-32 of co-pending application 10/630,206 is withdrawn in view of applicants' cancellation of the claims in the amendment filed March 29, 2006.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 1, 4, 5, 9 and 28-36, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claims, and applicants' response at page 5 in the amendment filed March 29, 2006.

Withdrawn Claim Rejections - 35 USC § 103

5. The previous rejection of claim 28, under 35 U.S.C. 103(a) as being unpatentable over Coe *et al.* (US 2001/0036943), is withdrawn in view of applicants' cancellation of the claim in the amendment filed March 29, 2006.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4, 5, 12, 13 and 29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Coe *et al.* (US 2001/0036943, based on provisional application 60/195,738 filed April 7, 2000).

Coe *et al.* disclose a method of treating a disorder or condition in which pain predominates including burn pain in a mammal by administering a pain attenuating effective amount of a pharmaceutical composition comprising a nicotine receptor partial agonist, an analgesic agent and a pharmaceutically acceptable carrier (paragraph [0272]), where a botulinum toxin can be used as an analgesic agent (paragraph [0001]; claims 1, 4, 5), and the composition can be administered locally including intramuscular administration (paragraph [0283]; claims 12, 13 and 29). Since the reference suggests the use of a botulinum toxin as the analgesic agent among a limited numbers of compounds for treating a pain condition such as burn pain, in which pain predominates, thus at the time of invention was made, it would have been obvious to one of ordinary skill in the art to administer a botulinum toxin to an mammal for the treatment of burn pain, which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Response to Arguments

Applicants indicate the Office Action identifies no "motivating force" that would "impel" a person of ordinary skill to pick out and combine the specific features randomly identified in the Coe reference to arrive at the present invention. The Coe reference discloses a method of treating acute, chronic and/or neuropathic pain and migraine in a mammal by administering a nicotine receptor partial agonist (NRPA) and an analgesic agent (e.g., botulinum toxin). The specification of the Coe reference discloses a long list of NRPAs and a long list of analgesic agents (see paragraphs [0006] to [0137]). The Office Action states that in view of the known properties and the use of botulinum toxin it is obvious that one of ordinary skill in the art would be able to selectively pick botulinum toxin for use in treating burn pain (see page 5). Applicant asserts that the Coe reference and other prior art knowledge would not impel one of ordinary skill to use a botulinum toxin to alleviate a burn pain, because, for example, the biochemical and neurological mechanisms of a burn pain may be very different from other types of pain. At most, it would be "obvious to try" the administration of a botulinum toxin to alleviate a burn pain. However, "obvious to try" is not the proper standard for obviousness. Since the Office Action has not provided any evidence or basis that would impel one of ordinary skill to pick the use of botulinum toxin to alleviate a burn pain, the Office Action has not established a prima facie case of obviousness (pages 6-8 of the response).

Applicants' response has been fully considered, however, the arguments are not found persuasive because of the following reasons. Coe teaches the use of a nicotine receptor partial agonist (NRPA) and an analgesic agent for treating acute, chronic or neuropathic pain, e.g., burn pain, where a limited numbers of analgesic agents including botulinum toxin are listed. Since burn pain is cited as a condition in which pain predominates (paragraph [0001]), and botulinum

toxin is listed with other limited numbers of compounds as an analgesic agent (paragraph [0272]), further, botulinum toxin A is known to have long duration (e.g., an efficacy for up to 12 months) and has been used to treat various pain conditions such as pain due to muscle spasm or migraine as evidenced in Aoki et al. (US 20040018214, paragraphs [0050]-[0052]), it is obvious that one of ordinary skill in the art would be able to pick botulinum toxin for use in treating burn pain. Applicants argue that the biochemical and neurological mechanisms of a burn pain may be very different from other types of pain, however, Coe also teaches the use of a nicotine receptor partial agonist and an analgesic agent such as botulinum toxin or other listed compounds to treat acute, chronic or neuropathic pain, which would include burn pain along with other types of pain (see paragraph [0272]), thus, Coe's teaching is not "obvious to try" but suggests the use of a nicotine receptor partial agonist and botulinum toxin to treat burn pain and other pain conditions.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Previous rejection of claims 1, 4, 5, 9, 12, 13 and 29-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 31-32 of co-pending application 10/630,206 (based on the amended claims filed June 22,

2005) is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 4, 5, 9, 12, 13 and 29-36 in the instant application disclose a method for treating or alleviating a burn pain, the method comprising local or peripheral administration of an effective amount a botulinum toxin to a mammal. This is obvious variation in view of claims 1, 4, 5, 9, 12, 13 and 31-32 of the co-pending application which disclose a method for treating a face pain, comprising peripheral administration such as intramuscular administration of an effective amount of a botulinum toxin to a mammal, wherein the face pain is not associated with a muscle disorder. Both sets of claims cite a method of treating pain such as burn pain, which may occur in the face, comprising peripheral administration of a botulinum toxin to a mammal. Thus, claims 1, 4, 5, 9, 12, 13 and 29-36 in present application and claims 1, 4, 5, 9, 12, 13 and 31-32 in the co-pending application are obvious variations of a method of treating pain such as burn pain, which may occur in the face, comprising peripheral administration of a botulinum toxin to a mammal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate as the rejection is provisional, they will address this issue in a subsequent response upon indication of otherwise allowable subject matter (page 5 of the response). Since applicants do not respond to the rejection, the rejection is maintained.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
April 12, 2006